REMARKS

Reconsideration of this application is respectfully requested. Claims 11-15 have been canceled without prejudice. Claim 1 has been amended to recite that the solid pharmaceutical composition includes tacrolimus in polyethylene glycol (PEG) and a poloxamer on a solid carrier. Support for this amendment is found at, for example, page 24, lines 26-27, of the specification. Claims 5-10 and 42 have been amended for clarity. Claim 16 has been amended to depend from claim 1 rather than canceled claim 15. Claim 57 has been added. Support for claim 57 can be found at, for example, original claim 38. No new matter has been added by these amendments.

Claims 1, 3–10, 16-29, 31–34, 36–44 and 51–57 are pending. As claims 38 and 39 have been withdrawn from consideration, claims 1, 3–10, 16–29, 31–34, 36, 37, 40–44 and 51–57 are currently at issue.

Withdrawn Claims 38 and 39 Should Be Examined in the Present Application

The October 8, 2009 Office Action states that claims 38 and 39 have been withdrawn from consideration. Applicants respectfully submit that claims 38 and 39 should be examined in this application.

In a December 19, 2007 Office Action, the Examiner required election of (1) a specific active ingredient, and (2) up to two vehicles. Applicants elected tacrolimus as the active ingredient, and PEG 6000 and poloxamer 188 as the vehicles (see the February 20, 2008 response). All of the pending claims, including claims 38 and 39, read on the elected species. Claims 38 and 39 ultimately depend from claim 1, which recites a composition comprising tacrolimus, PEG, and poloxamer. Claims 38 and 39 further recite specific water-miscible polymers, which are included in the composition as release modifying agents (according to claim 31, from which claim 38 depends). Accordingly, Applicants respectfully request that claims 38 and 39 be examined in this application.

Obviousness Rejection

Claims 1, 3–11, 13–29, 31–34, 36, 37, 40–44 and 51–56 have been rejected as obvious over Patel (US 2003/0180352) in view of Holm (WO 03/004001) and "Tacrolimus (Systemic)" (Drugs.com, August 1997, hereinafter "Drugs.com"). The Examiner contends that Patel teaches a solid dosage formulation comprising tacrolimus, PEG-24 cholesterol ether, distilled monoglycerides, and deoxycholic acid, coated on nonpareil seed having a diameter of about 400 to 500 μm (Office Action, p. 3-4).

Patel, however, is silent regarding how one of ordinary skill in the art would go about selecting additional components for use in any formulation, let alone a tacrolimus formulation. Nor does Patel provide any guidance regarding how to select particular active agents with other formulation components. Patel simply provides vast lists of formulation components, and does not teach how to select or combine the components to arrive at a workable dosage form. Therefore, upon considering Patel, one of ordinary skill would have had no reason or motivation to use the combination of PEG and poloxamer in any formulation, let alone a formulation containing tacrolimus as the active ingredient.

Holm does not cure this deficiency. Holm lists specific active agents for use with the controlled agglomeration method, but does not disclose tacrolimus as a suitable active agent (*see* Holm, pp. 13-19).

Further, the Drugs.com reference does not disclose or suggest that the delivery systems disclosed in Holm or Patel would be suitable or advantageous to use for tacrolimus. None of these references disclose or suggest that tacrolimus dispersed in a mixture of PEG and poloxamer on a solid carrier would provide sufficient dissolution and bioavailability of the tacrolimus.

For the foregoing reasons, the cited references do not render obvious the presently claimed invention. Accordingly, Applicants respectfully request withdrawal of this rejection.

Double Patenting Rejections

Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 have been provisionally rejected for obviousness type double patenting over (1) claims 1, 8, 10, 17-23, 26-32, 34, 36, 37, 63 and 64 of copending Application No. 10/513,807, (2) claims 1-50 of copending Application No. 11/885,992 and (3) claims 1-10 and 15-31 of copending Application No. 11/569,862.

Applicants respectfully request that these provisional rejections in abeyance until a claim is found allowable.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

Dated: December 31, 2009

Respectfully submitted,

By /Jay P. Lessler/
Jay P. Lessler
Registration No.: 41,151
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant